UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,427	07/29/2003	Michael J. Yaszemski	630666.91012	6019

26710 7590 02/08/2006

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,427	YASZEMSKI ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-16,18-22,24-28,31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33-37* is/are allowed.

6)☒ Claim(s) *1-3, 5-12, 14-16, 18-22, 24-26, 28, and 31* is/are rejected.

7)☐ Claim(s) *13 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 21 November 2005 have been fully considered but they are not persuasive. The Applicant argues that there is no suggestion or motivation for the combining of Hadlock with Juergensen. The Examiner disagrees. Hadlock discloses that nerve regeneration promoting substances can be provided within the internal lumens or within the polymer wall of the lumens to further promote nerve regeneration (col. 3, lines 37-31). Hadlock also teaches the desire for cell adhesion. Juergensen teaches that a proteoglycan degrading enzyme comprising chondroitinase ABC promotes adhesion (col. 7, lines 8-23). Chondroitinase ABC is known for its properties of promoting nerve regeneration (evidenced by 6972168).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5, 6, 12, 15, 16, 18, 19, 26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock et al. 5925053 in view of Juergensen et al. 5736132 as evidenced by Muir 6972168.

4. Hadlock et al. teaches an implant for bridging a gap in a severed spinal cord or nerve and for promoting nerve regeneration, the implant comprising: a matrix

comprising a biocompatible, biodegradable, polymeric material and a bioactive agent dispersed within the matrix, the matrix having a proximal end and a distal end (col. 1, lines 50-56; col. 3, lines 10-12; col. 3, lines 27-31); wherein the matrix includes a plurality of internal guidance channels extending between the proximal end of the matrix and the distal end of the matrix. It should be noted that Hadlock et al. fails to specifically teach wherein the bioactive agent is a proteoglycan degrading enzyme. Hadlock et al. does teach that nerve regeneration promoting substances can be provided within the internal lumens or within the polymer wall of the lumens to further promote nerve regeneration (col. 3, lines 37-31)

5. Juergensen et al. teaches using a proteoglycan degrading enzyme for promoting adhesion of tissue (col. 7, lines 8-23). Hadlock et al. teaches that adherence of tissue is desirable to promote cell growth (col. 1, lines 56-59). Therefore it would have been obvious to one having ordinary skill in the art to include the bioactive agent proteoglycan degrading enzyme of Juergensen et al. in the implant of Hadlock et al. to enhance tissue adherence and promote cell growth (nerve regeneration). It is also known that proteogyclan degrading enzyme is used for nerve regeneration as evidence by Muir (col. 3 – col. 4).

6. Hadlock/Juergensen teaches the implant as above wherein wherein the polymeric material is poly(lactide-co-gylycolide) (col. 1, lines 60-63); further comprising Schwann cells disposed within at least one of the plurality of guidance channels; wherein the guidance channels are arranged such that the guidance channels correspond to spinal cord tracts wherein the implant is positioned in a gap in a severed

spinal cord (col. 5, lines 21-24); Schwann cells disposed within at least one of the plurality of guidance channels, and a second bioactive agent other than Schwann cells is diposed within at least one of the plurality of guidance channels (col. 3, lines 10-12; col. 3, lines 27-31); wherein the proteoglycan degrading enzyme is chondroittinase; wherein the condroitinase is chondroitinase ABC (col. 7, line 8-23).

1. Claims 7-12, 14, 20-22, 24, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hadlock/Juergensen as applied to claims 1-3, 5, 6, 12, 15, 16, 18, 19, 26, and 31 above, and further in view of Shastri et al. 6471993.

2. Hadlock/Juergensen. teaches the implant of claim 1. It should be noted that Hadlock/Juergensen fails to teach wherein biocompatible, biodegradable, polymeric microspheres including a second bioactive agent are disposed within at least one of the plurality of guidance channels.

3. Shastri et al. teaches an implant with common microspheres for protecting and controlling the release rate of a bioactive agent (col. 22, line 18-34). Therefore, it would have been obvious to use the microspheres of Shastri et al. to protect the bioactive agent when the implant is being produced.

4. Hadlock/Juergensen/Shastri teaches the implant of claim 7 wherein; the microspheres comprise poly(lactide-co-glycolide) (col. 22, lines 18-34 PGLA); wherein the microshperes are suspended in a carrier (col. 23, lines 31-41).

Allowable Subject Matter

5. Claims 33-37 are allowable over the prior art of record.

6. Claims 13 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER